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$\cdot \Gamma$	APPLICATION NO.	FILING DATE		FIRST NAMED INVE	NTOR		ATTORNEY DOCK	ET NO.
_	09/508,67	0 03/28/	00 BOV	ITE		F	00060	
Г	0,23338	. :		HM12/0323	\neg		EXAMINER	
•	DENNISON	MESEROLE S	CHEINER	& SCHULTZ	, · -	CAM	PAGNE,J	

1619

DATE MAILED:

ART UNIT

03/23/01

PAPER NUMBER

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

		Application No.	Applicant(s)					
<i>L</i> "	Office Action Summer:	09/508,670	BONTE ET AL.					
	Office Action Summary	Examiner	Art Unit					
		Jean-Michel Campagne	1619					
 Period fo	The MAILING DATE of this communication appe	ears on the cover sheet with the co	rrespondence address					
A SHO THE N - Exten after: - If the - If NO - Failur - Any re	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Issions of time may be available under the provisions of 37 CFR 1.15 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period veron to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing dipatent term adjustment. See 37 CFR 1.704(b).	36 (a). In no event, however, may a reply be tiry within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).					
1)🖂	Responsive to communication(s) filed on 28 l	<u> March 2000</u> .						
2a)	This action is FINAL . 2b)⊠ Th	is action is non-final.						
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims								
4)⊠ Claim(s) <u>1-46</u> is/are pending in the application.								
	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)	5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1-46</u> is/are rejected.								
7)🖂	7)⊠ Claim(s) <u>21,22,35,36,38 and 39</u> is/are objected to.							
8) Claims are subject to restriction and/or election requirement.								
Applicati	on Papers							
9)🖂	9)⊠ The specification is objected to by the Examiner.							
10)	10) The drawing(s) filed on is/are objected to by the Examiner.							
11)	11) The proposed drawing correction filed on is: a) approved b) disapproved.							
12)🖂	12) The oath or declaration is objected to by the Examiner.							
Priority u	ınder 35 U.S.C. § 119							
13)🖂	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119(a)-(d) or (f).					
a)[☐ All b)☐ Some * c)☐ None of:		·					
	1. Certified copies of the priority document	ts have been received.						
	2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.								
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).								
Attachmen	t(c)							
15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s)								
16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152) 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.4 20) Other:								

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OATH/DECLARATION

1. The Oath/Declaration is objected to. It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to *patentability* as defined in 37 CFR 1.56.

Examiner respectfully suggests replacing "examination" with "patentability."

OBJECTIONS

- 2. The specification and Claims 21, 22, 35, 36, 38, and 39 are objected to because of the following informality: it is conventional practice in the art to italicize scientific plant names. Appropriate correction is respectfully requested for all instances.
- 3. Claim 21 contains the following superfluous language: "consisting of a substance" (line 4) and "of the" (repeated in line 5).

112 REJECTIONS

- 4. The following is a quotation of the second paragraph of 35.U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claim 23 is vague and indefinite because it is unclear as to what vitamins of "group A" and "group C" are.
- 6. Claim 24 recites the limitation "said mineral compound" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.
- 7. Claim 33 recites the limitation "said sugar" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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102 REJECTIONS

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 9. Claims 17-24, 26, 27, 31, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Arima et al. (U.S. Patent No.5,073,545).

Arima et al. disclose preparations for external application containing an effective amount of an ellagic acid component (Abstract). Ellagic acid or salts thereof may optionally be substituted with alkyl or alkoxy groups having 1-20 carbons, a polyalkylene oxide residue having 2-3 carbons, or a sugar residue (Abstract and col.1 line 67-col.2, line 57). Arima et al. disclose that salts of ellagic acid include salts with alkali metals, alkali earth metals, ammonium salts, and amine salts (col.2, lines 43-49). Specific examples of the inventive ellagic acid compounds are given in column 2, lines 58-64. Bath Agent 2 (col.11 line 65-col.12, line 7) comprises sodium ellagate, magnesium oxide, and vitamin E. Toilet Water 1 (col.5, line 65-col.6, line 4) includes 3,3',4-tri-O-methylellagic acid. Bath Agent 6 (col.12, lines 34-42) includes citric acid.

Thus, Applicant claims and Arima et al. discloses compositions used in a method of cosmetic care comprising one or more of the following (respectively): an ellagic acid salt; a magnesium compound; a vitamin; an ellagic alkoxy ether component; an alphahydroxy acid.

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103 REJECTIONS

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 11. Claim 29, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arima et al. (U.S. Patent No.5,073,545) as applied to claims 17-24, 26, 27, 31, and 34-36.

Arima et al. disclose (see discussion above). Arima et al. fails to disclose monoand polyacylates of ellagic acid. However, Arima et al. disclose that in order to adjust the lipophilic or hydrophilic property of ellagic acid, some of R₁-R₅ in formula I are long chained alkyl or alkoxy groups, residues of alkylene oxide condensates, or a given sugar residue (col.2, lines 15-64).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Arima et al. by making monoand polyacylates of ellagic acid, because of the expectation that desirable lipo- or hydrophilicities would be afforded by an appropriate acylation of ellagic acid to yield residues with long chained alkyl groups. Further, it would have also been obvious to modify ellagic acid with the given sugar residue or with *any* monocyclic sugar residue since clearly the intended modifications are made in the interest of desirable lipo- or

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hydrophilicities as suggested by Arima et al. and one of ordinary skill in the art would know to make the appropriate sugar substitution for a desired application.

12. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arima et al. (U.S. Patent No.5,073,545) as applied to claims 17-24, 26, 27, and 29-36 above in view of Yoshida et al. (U.S. Patent No.5,380,753).

Arima et al. disclose (see discussion above). Arima et al. fails to disclose the optional magnesium, manganese, or silicon mineral compounds claimed by Applicant. However, Arima et al. disclose that when the agents for external application of their invention are used as bath agents, there can be added at least one inorganic salt or acid (col.5, lines 43-54).

Yoshida et al. disclose a Bath Agent in Example 3 (col.4, lines 36-51) that comprises magnesium chloride.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have modified the composition of Arima et al. by adding magnesium chloride as taught by Yoshida et al. because of the expectation that the addition of said salt would render the composition suitable for use as a bath agent.

13. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arima et al. (U.S. Patent No.5,073,545) as applied to claims 17-27 and 29-36 above, in view of Hampel and Hawley (Encyclopedia of Chemistry, 3rd ed., 1973).

Arima et al. disclose (see discussion above). Arima et al. fails to disclose zinc

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and copper complexes of ellagic acid; however, Arima et al. disclose that salts of ellagic acid are made in the interest of solubility (col.2, line 49).

Hampel and Hawley disclose that a metal complex may be positively charged, negatively charged, or neutral, and further, that an electrically charged complex is more soluble in a polar solvent such as water and a neutral complex is less likely to be soluble in a polar solvent (p.291, ¶ 4-p.292, ¶ 1).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Arima et al. by making metal complexes of ellagic acid as taught by Hampel and Hawley, because of the expectation that an appropriate metal complex would afford a desirable and applicable solubility of said acid.

14. Claims 37, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arima et al. (U.S. Patent No.5,073,545) as applied to claims 17-36 above in view of Seguin et al. (U.S. Patent No.4,549,990) taken with Soler et al. (U.S. Patent No. 6,113,926).

Arima et al. disclose (see discussion above). While Arima et al. discloses some plant extracts as optional active substances (col.5, line 60-col.6, line 11), they fail to disclose an extract of *Pygeum africanum*.

Seguin et al. disclose plant extracts (Abstract). Seguin et al. disclose that sterols in solution and/or dispersion in esters can be applied directly in cosmetic or

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pharmaceutical compositions (col.3, lines 49-59). Example 4 (col.4, line 59-col.5, line 3) is an extract of *Pygeum africanum* that comprises sterols of good purity.

Soler et al. disclose a composition consisting of a plant extract rich in antiandrogenic sterols obtained from a group of plants that includes African plums (*Pygeum africanum*) and said composition can be used in topical formulations for cosmetic and pharmaceutical purposes (Abstract). The composition offers a mechanism to maintain certain functions and structures that deteriorate with aging or due to other reasons and the treatment of several metabolic or degenerative illnesses and control of the growth, aspect, development and/or growth of certain structures such as the hair, prostate, and skin (col.1, lines 5-15). Formulations 4-7 (col.5, line 49-col.6, line 41) comprise African plum and are useful for treating acne.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Arima et al. by further including a *Pygeum africanum* extract as taught by Seguin et al. and Soler et al., because of the expectation that said extract would contribute a desirable and applicable anti-seborrhea activity to said composition.

15. Claims 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arima et al. (U.S. Patent No.5,073,545) as applied to claims 17-39 above in view of Bonte et al. (U.S. Patent No.6,004,568) taken with Ancira (U.S. Patent No.5,874,463), and in further view of Levy et al. (U.S. Patent No.5,780,060).

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Arima et al. disclose (see discussion above). Arima et al. disclose that their inventive composition includes forms of creams and lotions (col.5, lines 12-16). Arima et al. fail to disclose the use of said creams and lotions in the treatment of skin conditions marked by insufficiencies of collagen.

Bonte et al. disclose cosmetic or pharmaceutical compositions comprising Bertholletia extract whereby said extract promotes the synthesis of collagen (Abstract). Bertholletia extracts contain tannins, particularly ellagotannin and gallotannins (col.4, lines 55-60). Example 7 is a skin-firming body care lotion and Example 11 is an antiaging cream (col.11, line 59-col.12, line 45).

Ancira disclose skin peel compositions (col.3, line 49-col.4, line 61). Dermal alterations due to application of the preferred embodiment of the invention include increased accumulation of dermal glycosaminoglycans and an accelerated formation of collagen (col.4, lines 15-22). The inventive composition further comprises ellagic acid (Claim 16, line 35).

Levy et al. disclose microcapsules and compositions containing them (Abstract).

Levy et al. disclose that plant polyphenols constitute an important group of natural substances with well-known anti-free radical and anti-oxidizing properties (col.1, lines 15-17). These compounds are capable of preventing the harmful effects of free radicals and hence have anti-UV, anti-aging, and anticarcinogenic biological activities; moreover, they possess properties which can be utilized in therapeutics, in particular in dermatology and for application to mucous membranes (col.1, lines 17-38). Said compounds thus have application to fields of cosmetics and pharmaceutics (col.1, lines

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39-40). Levy et al. give examples of said compounds which include gallotanins, ellagotannins, and ellagic acid (col.4, lines 1-19).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the ellagic acid comprising composition of Arima et al. in a method of treatment for collagen insufficiency as taught by the combined teachings of Bonte et al., Ancira, and Levy et al., because of the expectation that said composition would have had dermatologically active properties including a stimulating effect on collagen synthesis.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean-Michel Campagne whose telephone number is (703)305-1903. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703)308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4556 for regular communications and (703)308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1234.

Jean-Michel Campagne

Examiner Art Unit 1619

March 19, 2001